TruQuick™ Dengue NS1 10T

A rapid test for a qualitative detection of NS1 antigen of dengue virus in whole blood, serum or plasma.

REF **TQ4110** IVD **Rx Only**

INTENDED USE
TruQuick Dengue NS1 is a rapid immunoassay for the qualitative detection of NS1 antigen of Dengue virus in whole blood, serum, or plasma as an aid in the diagnosis of Dengue infections. A positive test should be confirmed with alternative testing and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Dengue is a flavivirus, transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world,[1] and causes up to 100 million infections annually.[2] Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash. NS1 is one of seven Dengue Virus nonstructural proteins which are thought to be involved in viral replication. NS1 exists as a monomer in its immature form but is rapidly processed in the endoplasmic reticulum to form a stable dimer. A small amount of NS1 remains associated with intracellular organelles where it is thought to be involved in viral replication. The rest of NS1 is found either associated with the plasma membrane or secreted as a soluble hexadimer. NS1 is essential for viral viability but its precise biological function is unknown. Antibodies raised in response to NS1 in viral infection can cross react with cell surface antigens on epithelial cells and platelets and this has been implicated in the development of Dengue Hemorrhagic fever.

TruQuick Dengue NS1 is a rapid test that utilizes a combination of Dengue antibody-coated colored particles for the detection of Dengue NS1 antigen in whole blood, serum, or plasma.

BIOLOGICAL PRINCIPLES
During testing, the specimen reacts with Dengue antibody-conjugate in the Test Cassette. The gold antibody conjugate will bind to Dengue antigen in the specimen sample which in turn will bind with Anti-Dengue NS1 coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind the antibody-antigen complex causing pale or dark pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The Test Cassette contains anti-Dengue NS1 antibody conjugated gold particles and anti-Dengue NS1 antibody coated on the membrane. Each cassette is packaged in a foil pouch.
- Buffer: A buffered solution containing Proclin as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge (for plasma only)
- Micropipette
- Timer
- Lancets (for fingerstick whole blood only)

PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
The kit can be stored at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The Test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick Dengue NS1 can be performed using whole blood, serum, or plasma. Collect and prepare whole blood, serum and plasma according to standard laboratory methods.
2. To collect **Fingerstick Whole Blood specimens**:
   - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

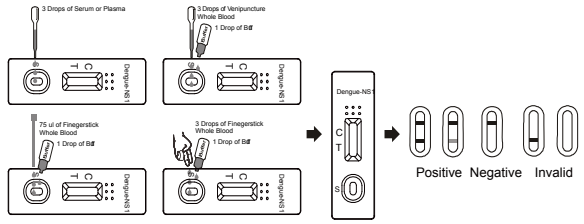
   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 75 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the Test Cassette.

   Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
   - Position the patient's finger so that the drop of blood is just above the specimen area of the Test Cassette.
   - Allow three hanging drops of fingerstick whole blood to fall into the center of the specimen area on the Test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 C for up to three days. For long-term storage, specimens should be kept below -20 C. Whole blood collected by venipuncture should be stored at 2-8 C if the test is to be run within two days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma specimen**:
   - Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 µL) to the specimen area, and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 µL) to the specimen area, then add 1 drops of Buffer (approximately 40 µL) and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and transfer approximately 75 µL of fingerstick whole blood specimen to the specimen area of Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer. See illustration below.
   - To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 µL) to fall into the specimen area of Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE: * Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Dengue NS1 antigen present in the specimen. Therefore, any shade of red in the test region should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new Test Cassette. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick Dengue NS1 has been compared with a leading commercial Dengue Ag EIA test. The correlation between these two systems is 96.0%.

LIMITATIONS OF THE PROCEDURE
1. The TEST PROCEDURE and the INTERPRETATION OF RESULTS sections must be followed closely when testing for the presence of dengue antigen in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. TruQuick Dengue NS1 is limited to the qualitative detection of dengue antigen in human whole blood, serum or plasma. The intensity of the test band does not linear correlate with dengue antigen titer of the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with dengue viruses.
4. A negative result can occur if the quantity of dengue antigen present in the specimen is below the detection limits of the assay, or the dengue antigen that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptom persists, while the result from TruQuick Dengue NS1 is negative or nonreactive, it is recommended to resample the patient few days late or test with an alternative test device such as PCR or ELISA.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick Dengue NS1 was tested with a seroconversion panel and compared with a leading commercial Dengue Ag EIA test using clinical specimens. The results show that the relative sensitivity of TruQuick Dengue NS1 is 95.8%, and the relative specificity is 96.1%.

Method		Dengue Ag EIA Test		Total Result
TruQuick Dengue NS1	Results	Positive	Negative	
	Positive	137	8	145
	Negative	6	200	206
Total Result		143	208	351

Sensitivity: 137/143*100% = 95.8% (95% CI*: 91.1%~98.4%);
Specificity: 200/208*100% = 96.1% (95% CI*: 92.6%~98.4%);
Correlation: (137+200)/(137+6+8+200)*100% = 96.0%(95% CI*: 93.4%~97.8%)
*Confidence Intervals

ANALYTICAL SENSITIVITY
TruQuick Dengue NS1 was tested with dilutions of NS1 antigen in plasma. The Limit of Detection was determined to be 250 ng/mL of the antigen.

REPRODUCIBILITY
Intra-Assay Precision
Repeatability was determined using 10 replicates of serum and plasma for each of four samples (negative, low positive, medium positive, high positive). The specimens produced the correct results > 99.9% of the time.
Inter-Assay Precision
Between lot precision was demonstrated in 10 replicates of serum and plasma for each of four samples (negative, low positive, medium positive, high positive) and three product lots. The results were consistent between lots. Sample were correctly identified > 99.9% of the time.

CROSSREACTIVITY
TruQuick Dengue NS1 was tested with samples from patients diagnosed with the following as confirmed by ELISA and clinical diagnosis: HAV, HBV, HEV, HCV, HIV, Syphilis, HAMA, RF, CMV, Mononucleosis, Rubella, Toxoplasmosis. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to Dengue positive and negative specimens:

Acetylsalicylic Acid 20 mg/dL	Acetaminophen: 20 mg/dL
Ascorbic acid 20 mg/mL	Creatine 200 mg/dL
Hemoglobin 1 g/dL	Albumin 2 g/dL
Gentisic acid 20 mg/dL	Caffine 20 mg/dL
Bilirubin 1 g/dL	Oxalic acid 60 mg/dL
Uric acid 20 mg/dL	Methanol 10%

REFERENCES

1. Halstead SB. Selective primary health care: strategies for control of disease in the developing world: XI, Dengue. Rev Infect Dis. 1984;6:251-264.
2. Halstead SB. Pathogenesis of dengue: challenges to molecular biology. Science 1988;239:476-481.

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SNTQ4110 **REV. 03/17**

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.